IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Dominik Meyer	)	Confirmation No. 2772
	)	
	)	Group Art Unit: 1616
Serial No.: 10/521,599	)	
	)	Examiner: Ernst V. Arnold
	)	
Filed: January 18, 2005	)	
	)	
Title: USE OF NEUROTOXIC SUBSTANCES FOR THE PRODUCTION OF A MEANS FOR THE TREATMENT OF JOINT PAIN AND METHOD FOR APPLICATION OF SAID MEANS	)	
	)	
Atty: Dkt.: LUS-15874	)	
	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PAPER PROVIDING SUMMARY OF CLAIMED SUBJECT MATTER AS REQUIRED BY 37 C.F.R. §41.37(c)(1)(v)
(In Response to Paper No./Mail Date 20090620)

Sir:

In the Office communication mailed on June 26, 2009, the Examiner held that the Appeal Brief filed on November 20, 2008 was defective solely because of a typographical error appearing on page 7 in the Summary of Claimed Subject Matter section of the Appeal Brief. Specifically, independent claim 40 was incorrectly typed as claim 43 in the Appeal Brief. Pages 2-4 of this Paper include a corrected Summary of Claimed Subject Matter, and should be substituted for pages 6-8 of the original Appeal Brief.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention discloses and claims a method for treating post-operative joint pain. Such pain often originates in the area of the joint capsule or in the bone area close to the joint (page 1, lines 10-11). Applicant's method focuses on pain that emanates from nociceptive nerve fibers in the area near the joint (page 1, lines 14-15). It is known that local anesthetics can be injected into a diseased joint at conventional concentrations to alleviate such pain, but the pain relief is of limited duration and usually recurs (page 1, lines 15-18).

Applicant has surprisingly found that it is possible to obtain long-lasting joint pain relief by injecting an unconventionally high concentration of a local amide anesthetic dissolved in a biocompatible solvent into a post-operative joint space as a one-time application. When introduced in this manner, the local amide anesthetic diffuses to the sensitive nerve endings which directly or indirectly innervate the region of the joint, and damages these nerve endings such that long lasting pain relief is obtained (page 3, lines 5-18). The joint capsule or the synovial pouch retains the high concentration of the local amide anesthetic at the site of pain generation, making it possible to retain the unconventionally high concentration of local amide anesthetic at the site of pain than would otherwise be possible if the joint capsule or the synovial pouch were not present, while simultaneously leaving the cavity/nerve structures and other structures near the joint relatively unaffected (page 3, lines 10-16). The unconventionally high concentration of local amide anesthetic is neurotoxic/neurolytic to the sensitive nociceptive nerve fibers in the joint space, but surprisingly is not systemically toxic (page 6, lines 11-13).

The present patent application contains two independent claims. In an effort to comply with 37 C.F.R. §41.37(c)(1)(v), both independent claims are recited below, with bold, italicized parenthetical information added thereto to show where the claimed subject matter is described in the specification:

> Claim 1: A method for treating post-operative joint pain, the method comprising:
>
> providing an agent for treating joint pain comprising a neurotoxic substance dissolved in a bio-compatible solvent (***page 9, lines 12***), wherein said neurotoxic substance is an amide local anesthetic (***original claim 5***), and wherein said

amide local anesthetic is present in said agent for treating joint pain in a concentration whereby said agent for treating joint pain is predominantly toxic to nociceptive nerve fibers but not systemically toxic when injected into a post-operative joint space (***page 6, lines 11-12***); and

injecting the agent for treating joint pain into said post-operative joint space (***page 12, lines 1 and 6***) as a one time application (***page 6, line 10***) in an amount sufficient to entail neurolysis (***page 6, lines 12-13; original claims 38 and 43***).

Claim 40: A method for treating post-operative joint pain, comprising:

injecting an agent comprising a neurotoxic substance dissolved in a bio-compatible solvent (***page 9, lines 12***) into the intra-capsular region or into the joint synovial pouch of the pain-afflicted joint (***page 3, lines 10-16***) as a one time application (***page 6, line 10***) at a concentration entailing neurolysis (***page 6, lines 12-13; original claims 38 and 43***), wherein the neurotoxic substance is an amide local anesthetic (***original claim 5***) and is present in said agent in a concentration whereby said agent is predominantly toxic to nociceptive nerve fibers but not systemically toxic (***page 6, lines 11-13***).

The patentability of dependent claims 6, 7 and 11-17 is separately argued herein. Accordingly, in an effort to comply with 37 C.F.R. §41.37(c)(1)(v), claims 6, 7 and 11-17 are repeated below with bold, italicized parenthetical information added thereto to show where the claimed subject matter is described in the specification:

Claim 6: The method as claimed in claim 5, wherein the pH-lowering additive is a bisulfite (***page 5, line 24***).

Claim 7: The method as claimed in claim 6, wherein the pH-lowering additive is sodium bisulfite ($NaHSO_3$) (***page 5, line 25***).

Claim 11: The method as claimed in claim 5, wherein the amide local anesthetic is lidocaine at a concentration larger than 6 % (***page 5, line 4***).

Claim 12: The method as claimed in claim 5, wherein the amide local anesthetic is prilocaine at a concentration larger than 3 % (***page 5, line 5***).

Claim 13: The method as claimed in claim 5, wherein the amide local anesthetic is mepivacaine at a concentration larger than 5 %.

Claim 14: The method as claimed in claim 5, wherein the amide local anesthetic is bupivacaine at a concentration larger than 1.5 % (***page 5, line 7***).

Claim 15: The method as claimed in claim 5, wherein the amide local anesthetic is levobupivacaine at a concentration larger than 5 % (***page 5, line 9***).

Claim 16: The method as claimed in claim 5, wherein the amide local anesthetic is ropivacaine at a concentration larger than 2 % (***page 5, line 10***).

Claim 17: The method as claimed in claim 5, wherein the amide local anesthetic is etidocaine at a concentration larger than 2 % (***page 5, line 11***).

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 18-0160, our Order No. LUS-15874.

Respectfully submitted,

RANKIN, HILL & CLARK LLP

By: /Randolph E. Digges, III/
Randolph E. Digges, III, Reg. No. 40590

38210 Glenn Avenue
Willoughby, Ohio 44094-7808
(216) 566-9700

July 13, 2009